



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0797]

The Food and Drug Administration Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards; Public Meeting and Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and establishment of docket.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to obtain comments that will inform our development of FDA Food Safety Modernization Act (FSMA) implementation work plans. FDA is also announcing a public meeting entitled “FDA Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards.” At the public meeting, we will share our current thinking on our operational strategy for implementation work plans. We will also provide interested persons an opportunity to provide input on this operational strategy and the risk-based industry oversight framework that is at the core of FSMA.

DATES: See section III, “How to Participate in the Public Meeting” in the SUPPLEMENTARY INFORMATION section of this document for dates and times of the public meeting, closing dates for advance registration, requesting special accommodations due to disability, and

information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management.

ADDRESSES: See section III, "How to Participate in the Public Meeting" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meeting or to register by phone: Courtney Treece, Planning Professionals Ltd., 1210 West McDermott Dr., suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: ctreece@planningprofessionals.com.

For general questions about the meeting or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act to establish the foundation of a modernized, prevention-based food safety system. Among other things, FSMA requires FDA to issue regulations regarding produce safety, preventive controls for foods for humans and animals, intentional adulteration, the foreign supplier verification program (FSVP), and the FDA third-party accreditation program.

While FSMA reinforces industry's primary role and responsibility for food safety, it also builds on and strengthens FDA's oversight role in establishing food safety standards, fostering

compliance with those standards through guidance and technical assistance, and enforcing the standards to protect public health when problems occur. In fact, more so than ever before, we are called upon by FSMA to play a central leadership and operational role in the future global food safety system. Meeting this challenge--and successfully implementing FSMA's new prevention-oriented, systems approach to food safety--necessitates a new strategy for how we perform our food safety role and meet our new responsibilities.

On May 2, 2014, we released our "Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)," available electronically at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>, to guide the next phase of FSMA implementation. The operational strategy broadly outlines our approach to food safety and the operational strategy for our food safety program and implementation of FSMA after the rulemaking is complete. Within the "Operational Strategy for Implementing FSMA," there is an appendix that outlines guiding principles for how the operational strategy can be implemented with respect to food and feed facilities, produce safety standards, and import oversight. The guiding principles include the following: expanding inspection and surveillance; administering new administrative enforcement tools; developing guidance, education, and technical assistance tools; and building a prevention-oriented import system.

The public meeting is an opportunity for interested persons to share views concerning how FDA should address the operational aspects of FSMA implementation as suggested by the guiding principles. However, the guiding principles do not lay out an exhaustive list of operational issues to be considered. Therefore, interested persons will have an opportunity at the public meeting to share views and suggest new ideas on a range of operational issues that FDA might consider in our FSMA implementation approach. Furthermore, the public meeting is an

opportunity for FDA to share our current thinking on our implementation plans. We encourage interested persons to provide feedback on any ideas that we present at the public meeting related to the operational aspects of FSMA implementation. We are also establishing a docket to obtain comments that will inform our development of FSMA implementation work plans. The agenda and other documents will be accessible on our FSMA Web site at <http://www.fda.gov/FSMA> before the public meeting.

II. Purpose and Format of the Public Meeting

FDA is holding this public meeting on FSMA implementation to provide an update on current planning efforts and to receive input from the public to inform the development of operational work plans in the areas of produce safety, preventive controls for foods for humans and animals, measures to address intentional adulteration, FSVP, and the FDA third-party accreditation program. Please note that input received previously through our continued engagement with interested parties as part of the FSMA proposed rules' rulemaking process will also be considered in the development of operational work plans. However, the Agency will not accept any new information or data submitted during the public meeting or through the docket to inform any rulemaking.

FDA will provide multiple opportunities for individuals to actively express their views. At the meeting, following introductory presentations by FDA, stakeholders will have an opportunity to participate in their choice of breakout sessions on the topics discussed at the meeting and engage in an open comment and question and answer session. Interested parties may also submit electronic or written comments to the docket by May 26, 2015. Breakout sessions will cover operational aspects of produce safety, preventive controls for human and animal food, intentional adulteration, FSVP, and the FDA third-party accreditation program, as

well as overarching topics. We invite the public to provide information, share experiences, and raise issues on topics that will be addressed in the breakout sessions including (but limited to): increasing awareness/reaching the regulated community, potential partners on outreach and implementation, state of readiness, barriers to implementation, training and education for industry and regulators, guidance needs, promotion of best practices, technical assistance, data needs, inspection changes/approaches, compliance and enforcement issues, and long-term implementation success.

There will be an opportunity for stakeholders who are unable to participate in person to join the meeting via Web cast. (See section III of this document for more information on the Web cast option.)

III. How to Participate in the Public Meeting

FDA is holding the public meeting on April 23, 2015, from 8:30 a.m. to 5:30 p.m. and April 24, 2015, from 8:30 a.m. to 12:30 p.m. Due to limited space and time, we encourage all persons who wish to attend the meeting to register in advance. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated. While there is not a formal comment session planned for the public meeting, it is anticipated that stakeholders will have ample opportunity to provide comments and opinions during the public meeting through their participation in breakout sessions and in the dialogue and question and answer session.

Table 1 of this document provides information on participation in the public meeting.

Table 1.--Information on Participation in the Meeting and on Submitting Comments to the Docket

	Dates	Electronic addresses	Addresses	Other information
Attend public meeting	April 23, 2015, from 8:30 a.m. to 5:30 p.m., and April 24, 2015, from 8:30 a.m. to 12:30 p.m.	Please preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	Washington Marriott at Metro Center, 775 12th St. NW., Washington, DC 20005	Registration check-in begins at 8 a.m.
View Web cast	April 23, 2015, from 8:30 a.m. to 5:30 p.m., and April 24, 2015, from 8:30 a.m. to 12:30 p.m.	Individuals who wish to participate by Web cast are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .		The Web cast will have closed captioning.
Preregister	Register by April 16, 2015	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm .	We encourage the use of electronic registration, if possible. ¹	There is no registration fee for the public meeting.
Request special accommodations due to disability	Request by April 8, 2015	Juanita Yates, email: Juanita.yates@fda.hhs.gov .	See FOR FURTHER INFORMATION CONTACT.	
Submit electronic or written comments	Submit comments by May 26, 2015	Federal eRulemaking Portal: http://www.regulations.gov . Follow the instructions for submitting comments.	Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852	Identify your comments with the docket number listed in brackets in the heading of this document. We encourage you to submit electronic comments by using the Federal eRulemaking Portal.

IV. Comments, Transcripts, and Recorded Video

¹ You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Courtney Treece, Planning Professionals Ltd., 1210 West McDermott Dr., suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: ctreece@planningprofessionals.com.

Regardless of attendance at the public meeting, interested persons may submit to FDA's Division of Dockets Management (see Addresses in table 1 of this document) either electronic or written comments on FSMA implementation issues. You only need to send one set of comments. Identify the comments with the docket number listed in brackets in the heading of this document. However, we will not use any information or data submitted during the public meeting or through the docket to inform any FSMA rulemakings where the comment periods have closed.

With respect to transcripts, please be advised that as soon as a transcript is available it will be accessible at <http://www.regulations.gov> and at FDA's FSMA Web site at <http://www.fda.gov/FSMA>. You may also view the transcript at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Additionally, we will be video recording the public meeting. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at <http://www.fda.gov/FSMA>.

Dated: March 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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